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SHORT-TERM EVALUATION

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INTRAORAL SOFT SPLINTS

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A Thesis

Submitted to the Faculty of the Graduate School

of the University of Minnesota

By

Edward Francis Wright

In Partial Fulfillment of the Requirements

for the Degree of

Master of Science

June, 1994

DEDICATION

To my family for allowing me to return to school.

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My extreme gratitude to Dr. John Schulte for all of the support, understanding and kindness he has given me throughout the entire TMJ and Craniofacial Pain Program.

A sincere thanks to Dr. Gary Anderson for all of his inspiration, encouragement and guidance with this thesis and treating patients in the TMJ and Craniofacial Pain Clinic.

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INTRODUCTION

Chronic pain is the most disabling and expensive nonmalignant illness in the industrialized world (Hampf, 1992). It costs society over 80 billion dollars annually in lost work, health care and medications (Fricton et al. 1988). A 1986 Lou Harris poll found that the most common reason people missed work was due to head pain (Fricton, 1991a). One of the most common sources of chronic head pain disorders are temporomandibular disorders (TMD). It is estimated that 25-73% of the industrialized population will suffer from a TMD at sometime during their life (Hampf, 1992).

Temporomandibular disorders are a group of musculoskeletal problems that involve the masticatory muscles and/or the temporomandibular joint (TMJ). Treatment is usually palliative in nature rather than curative and generally involves multiple therapies (Clark et al. 1990b).

One of the most common therapies prescribed by dentists for TMD is an intraoral occlusal appliance (Glass et al. 1991). Intraoral occlusal appliances can be hard or soft. The hard occlusal appliances are generally fabricated in a dental laboratory, but can be made intraorally with self-curing acrylic (Bates et al. 1984). The soft splints can be made from silicone rubber impression material (Hicks, 1989) or soft vinyl sheets (Williams, 1992). Preformed moldable vinyl occlusal appliances are also available and some even have fluid filled pouches (Lerman, 1987). Scientific studies demonstrating the effectiveness of intraoral occlusal appliances have generally focused on the hard acrylic

occlusal appliances that are fabricated in the laboratory. There have been no randomized clinical trials demonstrating the effectiveness of the soft occlusal appliances (Okeson, 1993). Clinically, many practitioners have found soft splints beneficial and recommend their use in the treatment of TMD (Campbell, 1957; Posselt and Wolf, 1963; Block et al. 1978; Ahlin et al. 1984; Clark, 1984; Zarrinnia and Lang, 1984; Singh and Berry, 1985; Guinn and Williams, 1985; Harkins et al. 1988; Wright, 1988; Dawson, 1989; Hicks, 1989; Quayle et al. 1990; Shulman and Zeno, 1990; Ahlin, 1991; Bledsoe, 1991; Colt, 1991; Williams, 1992). There is disagreement in the literature over the effectiveness of soft intraoral occlusal appliances (Harkins et al. 1988; Okeson, 1993). Singh and Berry (1985) and Harkins et al. (1988) have also suggested that occlusal changes may occur with the use of soft intraoral occlusal appliances. There is need for a well designed clinical trial to evaluate the effectiveness of the soft intraoral occlusal appliances. Such a trial could include an evaluation of changes in dental occlusion during treatment.

The purpose of this study was to evaluate the effectiveness of soft intraoral occlusal appliances and palliative treatment in the treatment of masticatory muscle pain. A secondary objective was to assess the effect of the appliances on occlusal contacts.

REVIEW OF LITERATURE

The use of intraoral occlusal appliances has been advocated in the dental literature for over 90 years (Goodwillie, 1881; Bates et al. 1984). In its early evolution, many materials were tried including the insertion of thin cork wedges between the teeth (Bell, 1989). Today intraoral occlusal appliances are usually soft vinyl or hard acrylic splints that fit over teeth on the maxillary or mandibular arch (Colt, 1991).

Intraoral occlusal appliances are advocated to eliminate occlusal discrepancies, reduce bruxism and parafunctional activities, prevent wear and mobility of the teeth, deprogram the neuromuscular system, reduce abnormal muscle activity and correct derangements of the TMJ (Clark, 1984; Harkins et al. 1988; Boero, 1989; Clark et al. 1990a; Pertes and Cohen, 1992). Through splint therapy, control over which teeth occlude in various mandibular positions, the degree of elevator muscle elongation and the relation of the condyle to the disc and fossa in maximum intercuspation can be realized (Boero, 1989; Klineberg, 1991).

All splints have potential complications associated with them. In addition to the problems with speech and esthetics of which the patients are most cognizant, patients may also develop irreversible changes in their occlusal contacts, caries or gingival inflammation under their splints, increased salivation and psychological dependence on the appliance (Brayer and Erlich, 1976; Clark, 1984; List and Helkimo,

1992).

SPLINT DESIGNS

Each splint design has distinct advantages and disadvantages (Boero, 1989). Most studies that have evaluated splint design have used surface EMG (usually over the temporalis and masseter muscles) for outcome measurement.

Surface EMG has some inherent difficulties that must be considered when evaluating a splint design. Surface EMG is not conducive to capturing the subject's natural physiological activity, has subject to subject variations and its mean frequency does not have a linear relationship with clenching strength (Hagberg and Hagberg, 1988; Widmer et al. 1990). In spite of these difficulties, surface EMG is capable of providing immediate numerical values independent of clinician's bias to evaluate splint designs at varied mandibular positions (Widmer et al. 1990). Interestingly, splint designs recommended through surface EMG testing are similar to those utilizing gnathological principals, used by dentists for many years (Dawson, 1974).

The mandible's centered position (centric relation) is considered to be the most stable musculoskeletal position for the mandible (Okeson, 1993). Some researchers believe the ideal occlusal splint should provide stability to the mandible in this position, enabling the muscles of mastication responsible for mandibular closure to exert maximal force

in centric relation. They recommend splint designs that allowed the subjects to produce the maximal surface EMG activity with clenching in centric relation (Wood and Tobias, 1984; Miralles et al. 1987; Miralles et al. 1988).

These investigators also thought that patients should be capable of applying less force in unstable excursive positions (non-centered positions) and recommended splint designs that allowed the subjects to produce the least voluntary clenching surface EMG activity in these positions (Shupe et al. 1984; Graham and Rugh, 1988).

ARCH COVERAGE

Splints can be made to cover an entire dental arch or only a portion of it. Miralles et al. (1988) tested maximum voluntary clenching using surface EMG activity for appliances with varied dental arch coverage. They fabricated splints divided into three sections (anterior and right and left posterior) and compared all combinations using eight subjects. They found that bilateral posterior splint coverage was needed for the subjects to produce maximum surface EMG activity in the temporalis and masseter muscles with voluntary clenching. Dahlstrom et al. (1985) also demonstrated that the resting surface EMG of the masseter and temporalis muscles were lower after wearing the full arch splint one week than wearing an anterior bite splint. A full arch splint is reported to best minimize dental occlusal changes (Clark, 1984; Boero, 1989). These studies suggest that a full arch splint is more effective and has less iatrogenic risk than a partial coverage splint.

CENTRIC STATIC POSITION

Miralles et al. (1988) demonstrated that maximum clenching surface EMG activity could be produced only when occlusal contacts were provided on stable posterior segments. Conversely, if the contacts were only on the anterior segment, only 40% of the maximum surface EMG activity could be achieved. They also reported that the contacts need to be bilateral and symmetrically distributed with equal intensity over the posterior teeth. Bakke and Michler (1991) corroborated the findings of Miralles et al. (1988) by demonstrating that equilibrated posterior splint surfaces increase the maximum voluntary surface EMG clench. These studies suggest if a full coverage splint is used, it should have evenly distributed bilateral posterior contacts with light or no contact on the anterior teeth when in centric position.

EXCURSIVE OCCLUSAL GUIDANCE

As the mandible moves from its centered position (centric relation), teeth opposing the splint slide along the excursive occlusal guidance of the splint. This guidance can be steep or shallow, localized to a single tooth or distributed over a dental segment and located anywhere on the occlusal surface of the splint. Since excursive positions are unstable musculoskeletal positions, researchers believe that the ideal occlusal splint should allow the subject to produce the minimal voluntary clenching surface EMG activity in excursive positions (Shupe et al. 1984; Graham and Rugh, 19[illegible]).

Williamson and Lundquist (1983) evaluated two types of excursive

occlusal guidances using the surface EMG activity over the masseter and temporalis muscles. Splints with posterior disclusion by anterior guidance and posterior contacts during excursive movements were compared. They found splints with posterior disclusion by anterior guidance produced significantly lower muscle activity in the subject's masseter and temporalis muscles when the subject clenched in the excursive positions. Shupe et al. (1984) determined the lowest surface clenching EMG activity was achieved with a steep canine guidance, compared to flat guidance (9% higher) or group function (38% higher).

Four different occlusal designs (group function, canine guidance, working side occlusal interference and hyperbalancing occlusal interferences) were evaluated by Belser and Hannam (1985) using surface EMG activity over the masseter and temporalis muscles. Their results concurred with Shupe et al. (1984). Group function allowed a higher surface EMG activity than cuspid guidance. With parafunctional clenching, splints with hyperbalancing occlusal interferences resulted in the highest surface EMG activity while cuspid guidance splints were associated with the lowest. These results suggest that a canine-protected occlusion significantly reduces the muscle activity during parafunctional clenching.

Graham and Rugh (1988) reported no significant difference in maximum clench surface EMG levels between a first molar guidance and cuspid guidance. Rugh et al. (1989) corroborated these findings through clinical exams and subjective pain ratings of eight subjects.

Miralles et al. (1987) evaluated protrusive guidance. They

demonstrated that the fewer teeth that came in contact during protrusive movement, the lower the muscle activity. When the protrusive contact was limited to the mesioincisal portion of the central incisors, the surface EMG activity was just 18% of maximum voluntary intercuspal position clench in the temporalis muscle, compared to 39% for group function anterior guidance.

It has been suggested that elevator muscular inhibition may come from the periodontal membrane mechanoreceptors (Wood and Tobias, 1984; Manns et al. 1987, 1991; Miralles et al. 1987, 1988; Graham and Rugh, 1988; Boero 1989). These receptors are sensitive to pressure, which inhibits the elevator muscle motor neurons and activates jaw-opening muscle motor neurons, thereby protecting the teeth from excessive load (Hannam, 1982; Manns et al. 1987; Manns et al. 1991). In an experiment where the periodontal membrane mechanoreceptors were stimulated in cats, they were shown to cause a jaw-opening reflex (Boero, 1989).

Mason et al. (1985) reported that the jaw-opening reflex inhibits the masseteric motoneurons and suggested habituation occurs with continuous stimulation of this reflex. The investigators continuously stimulated the jaw-opening reflex on the human subjects for one-half hour and found that the subjects not only reported that they were experiencing less pain from the stimulation but the recordings of their masseteric inhibition had also reduced in magnitude.

A study with humans comparing the maximum clenching in anesthetized and non-anesthetized mouths, Van Steenberghe and De Vries (1978) found that subjects could clench much harder than with dentoalveolar nerve

blocks. In fact the experiment had to be stopped on several subjects because they produced such high clenching forces that the investigators were afraid the subjects would permanently harm themselves. The study was repeated by Manns et al. (1991) who corroborated their results. Ito et al. (1986) and MacDonald and Hannam (1984) also theorized that pressure receptors within the temporomandibular joints will limit voluntary clenching.

The patient's maximum clenching forces in excursive position may be limited by mechanoreceptors within the TMJ and periodontal membrane as well as a decrease in the biomechanical stability from fewer tooth contacts. Evidence suggests that developing posterior disclusion through the least number of anterior teeth possible, should help to reduce the muscle activity when the patient performs parafunctional clenching in these unstable excursive positions.

VERTICAL DIMENSION

Splint thickness influences mandibular position, so that the thicker the splint, the greater the tooth separation with rest position and the longer the resting length of the elevator muscles (Manns et al. 1983).

Varied skeletal muscle lengths result in different magnitudes of EMG activity even though muscle force output remains constant. Muscle length plotted against surface EMG activity for a constant force results in a shape that approximates a parabola with its open ends pointed upward (see Figure 1). The vertex of the parabola represents the muscle length of maximum efficiency (Boero, 1989).

To evaluate the effect of thicker occlusal splints on TMD symptoms, Mann et al. (1983) randomly assigned 75 TMJ patients to three groups with flat plane occlusal splints. One group was treated with splints that increased their vertical dimension by one millimeter, the second group to one-half of the vertical distance from centric occlusion to where the masseter muscles had their minimum surface EMG activity and the third group to the vertical dimension of minimal masseter surface EMG activity. The third group experienced the most rapid reduction in TMD symptoms, the second group took slightly longer, and the first group took the longest time. This study suggested that thicker splints may resolve TMD symptoms more quickly.

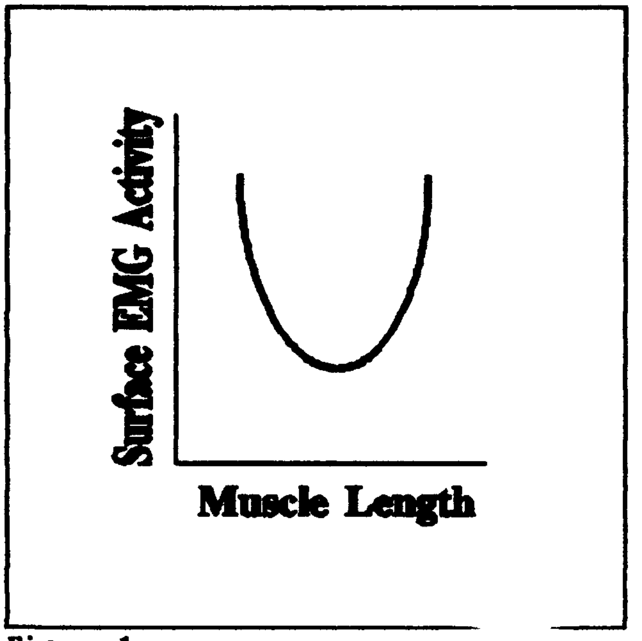

Figure 1

ARCH PREFERENCE

Patients are reported to prefer mandibular splints over maxillary splints because they are easier to speak with, are less visible, and produce less psychological stress for the patients (Tanner, 1980; Guinn and Williams, 1985; Verban, 1986; Taddey, 1990). Patients also report that a mandibular splint feels less obtrusive than a maxillary splint

(Zarrinnia and Lang, 1984; Wright, 1988). Harkins et al. (1988) found that 71% of his patients preferred the mandibular splint over the maxillary splint.

SOFT SPLINTS

Soft splints can be made for the maxillary or mandibular arches and can be fabricated with any occlusal contact scheme. Soft splints are not recommended for long term use without close supervision (Harkins et al. 1988). Soft splints have been advocated for patients with temporomandibular dysfunction (Campbell, 1957; Posselt and Wolf, 1963; Block et al. 1978; Ahlin et al. 1984, 1988; Clark, 1984; Zarrinnia and Lang, 1984; Singh and Berry, 1985; Guinn and Williams, 1985; Verban, 1986; Lerman, 1987; Harkins et al. 1988; Wright, 1988; Dawson, 1989; Hicks, 1989; Giedrys-Leeper, 1990; Quayle et al. 1990; Shulman and Zeno, 1990; Ahlin, 1991; Bledsoe, 1991; Colt, 1991; Messing, 1991; Williams, 1992; Okeson, 1993), but there are few scientific studies that have evaluated their effectiveness and results have been contradictory (Nevarro et al. 1985; Okeson, 1987; Harkins et al. 1988).

SOFT SPLINT INDICATIONS

Soft splints are easily constructed and are often inserted at an initial appointment. This is beneficial for an acute sprain or muscle spasm when the practitioner desires immediate use of an intraoral

occlusal appliance, especially if it may be some time before the fabrication of an acrylic splint can be accomplished (Bates et al. 1984, Hicks, 1989; Messing, 1991). The immediate availability of soft intraoral occlusal appliances has been used for emergency intraoral occlusal appliances to replace badly worn or broken splints for patients who are dependent on them (Hicks, 1989). Harkins et al. (1988), Wright (1988) and Hicks (1989) reported the use of soft splints as interim occlusal appliances until acrylic splints can be provided.

Since soft splints are readily available and inexpensive (Singh and Berry, 1985; Lerman, 1987; Ahlin et al. 1988; Harkins et al. 1988; Giedrys-Leeper, 1990; Ahlin, 1991; Messing, 1991), they have been recommended as a prognostic tool to evaluate whether acrylic splint therapy would be beneficial. Harkins et al. (1988) found that 93% of the 42 patients who reported a reduction in symptoms with the soft splint, had good to excellent results with the acrylic splint over a three to six month treatment period.

Dawson (1989) described the use of soft splints for patients with tooth pain related to chronic sinusitis. He speculated that maxillary posterior teeth which are close to the sinus could move slightly with changes in maxillary sinus pressure. Okeson (1993) reported that the teeth of these patients can become extremely sensitive to occlusal forces and the soft splint helps decrease their symptoms while definitive sinus treatment is pursued.

Soft splints are also extremely beneficial for patients who are in the mixed dentition phase, because these splints allowed for minor

movement of the teeth, while the acrylic splints require continual adjustments (Giedrys-Leeper, 1990).

It has been suggested that soft splints have a high degree of patient acceptance due to their "comfortable" cushion feel and may be tolerated even when acrylic splints can not (Zarrinnia and Lang, 1984; Verban, 1986; Wright, 1988; Giedrys-Leeper, 1990; Shulman and Zeno, 1990). Verban (1986) and Okeson (1993) reported that the softness may help dissipate some of the heavy loading that occurs during parafunctional activity.

SOFT SPLINT EFFICACY

Harkins et al. (1988) evaluated the soft splint's efficacy in patients with clicking temporomandibular joints. They provided 42 patients with soft splints to wear 10 to 20 days while their acrylic splints were being fabricated. They followed 42 other patients for approximately the same length of time who were not provided soft splints. Harkins et al. (1988) found that of the patients who wore the soft splints, clicking was reduced or eliminated in 74%, facial myalgia was reduced in 74%, cervical myalgia reduced in 73%, ear pain reduced in 63%, and tinnitus reduced in 71%. They found no appreciable change in the patients who were not provided soft splints. Harkins et al. (1988) found that the most common complaint they received from subjects was soft splint bulkiness.

Ahlin et al. (1988) found a similar decrease of clicking in the temporomandibular joints with soft splint use. They provided 35

patients with soft splints and used an electronic stethoscope to record the click's amplitude. They found that 69% of their subjects had a decrease in joint noise.

Block et al. (1978) evaluated 19 patients with nonspecific TMD symptoms for the overall effectiveness of soft splints. They found that after six weeks of use 74% had complete or almost complete remission of their TMD symptoms.

Some investigators believe TMD pain is a trigger for migraine attacks and treatment for TMD reduces the incidents of attacks (Okeson, 1993). Ahlin et al. (1984) demonstrated the effectiveness of soft splints in treatment of migraine headaches. Of 42 patients suffering from migraine headaches, 83% reported reduced severity and 79% reported reduced frequency. Quale et al. (1990) provided soft splints to 44 patients who suffered from migraine or tension vascular headaches. Eighty-two percent of these patients were significantly improved or cured of their vascular headaches by the use of the soft splints. Patients who also had TMD symptoms, found improvement in their TMD symptoms.

Many other anecdotal reports of soft splint efficacy are presented in the literature (Posselt and Wolf, 1963; Ahlin et al. 1984; Zarrinnia and Lang, 1984; Verban, 1986; Lerman, 1987; Wright, 1988; Hicks, 1989; Giedrys-Leeper, 1990; Shulman and Zeno, 1990; Ahlin, 1991; Bledsoe, 1991; Colt, 1991; Williams, 1992).

Nevarro et al. (1985) and Okeson (1987) are often cited as evidence for the ineffectiveness of the soft splints (Okeson, 1993). Nevarro et

al. (1985) randomly assigned twenty patients into two groups and followed them for three months. One group of ten patients was provided with acrylic splints adjusted to bilateral cuspid guidance and given weekly occlusal adjustments of their splints. The other group of ten patients was provided soft splints. Nevarro et al. (1985) reported the weekly adjustment of the soft splints "consisted of a mock adjustment since it is not possible to properly adjust this type of occlusal splint." In the group that receive the acrylic splints, nine improved and one remained the same, while in the soft splint group, three improved, one remained the same and six had an increase in morning soreness.

Okeson (1987) provided ten bruxism patients with hard and soft splints in a design where all of the subjects wore the hard splint for seven consecutive nights, subsequently wore no splint for five consecutive nights and then wore the soft splint for seven consecutive nights. He adjusted the acrylic splints in centric and excursive movements as recommended by the literature and adjusted the soft splint's occlusion until patients reported that all mandibular teeth evenly contacted the splint during light closure. He stated "No attempt was made to control eccentric contacts as this was nearly impossible" and he showed a photograph of the occlusal surface of one of his soft splint with the occlusion paper markings and obvious gross occlusal discrepancies. Okeson (1987) found that eight of the ten patients had significantly reduced their muscle activity when they used the acrylic splint but five of the same ten patients significantly increased their

muscle activity when they used the soft splint.

SOFT SPLINT OCCLUSION

Soft splint material has different handling characteristics than acrylic splint material and many practitioners familiar with acrylic splint adjustments, find adjusting soft splints difficult (Nevarro et al. 1985). The soft splint's resilient characteristics enable a poorly adjusted splint to be less traumatic to the opposing dentition than a poorly adjusted acrylic splint and therefore many practitioners have reported that soft splints do not require adjustments. Messing (1991) reported that the soft splint, just as the acrylic splint, must be adjusted or it will fail to relieve symptoms and may even aggravate the disorder. The ineffectiveness of poorly adjusted soft splints has actually been demonstrated through the studies that are often sighted as evidence that soft splints are not effective. These studies made limited attempts to properly adjust the appliances, which may have contributed to the poor treatment effect observed (Nevarro et al. 1985; Okeson, 1987).

There is general agreement that adjusting the occlusion of a soft splint in the same manner as an acrylic splint, creates a very poor or inaccurate occlusal surface on the soft splint (Boero, 1989; Okeson, 1993). There have been a few papers published explaining that soft splints have different characteristics than acrylic splints and with different methods may be occlusally adjusted (Wright, 1988).

Harkins et al. (1988) found "transient" occlusal changes in some of

their patients given soft splints. One of the major complaints Harkins et al. (1988) received from noncompliant patients was the poor fit of the appliance. Harkins et al. (1988) provided their patients with preformed soft splints that did not have lingual flanges and could not be adapted to tightly form around the buccal surfaces of the teeth. One of the basic principals of prosthodontic design is that a removable appliance must circumscribe all teeth it rests against or tooth movement may occur (McGivney and Castleberry, 1989). Since the soft splints used by Harkins et al. (1988) only had an occlusal and buccal surface, they could have allowed movement of the teeth.

Singh and Berry (1985) also found changes in the occlusion when they used the soft splint. The purpose of their experiment was to measure occlusal changes that could occur with mechanical interferences of the occlusal splints. Three, five and seven hours following the insertion of the soft splints they measured the changes in the number of occlusal contacts. They reported soft splints are less likely to cause occlusal changes than acrylic splints and recommended the use of soft splints for treating TMD.

PALLIATIVE TREATMENT

Palliative treatment involves self-care with patient instructions that routinely include (McNeill, 1993):

1. Encourage the patient to rest the masticatory muscles by voluntarily limiting the activities for which the patient uses these muscles, i.e., avoiding hard or chewy foods and restraining from activities that overuse the muscles of mastication (yawning, yelling and prolonged dental appointments).

2. Encourage awareness of oral habits and modifying them, i.e., changing a clenching habit to lightly resting their tongue behind their maxillary anterior teeth and keeping their masticatory muscles relaxed.

3. Instituting a home physiotherapeutic program, i.e., applying heat or cold to the most painful masticatory areas.

Hodges (1990) provided temporomandibular dysfunction patients with the American Dental Association's TMJ disease pamphlet, information about their disorder's relationship to stress and muscle spasm, and self-care instructions emphasizing heat and massage along with recommendations for the use of ibuprofen or propoxyphene with acetaminophen as needed. Seventy-five percent of these patients were pain free or comfortable with their problem and management.

Randolph et al. (1990) provided 15 patients with only self-care and 95 patients with conservative treatment in addition to self-care. Through telephone interviews one to seven years later, they found that

of the patients who only received self-care 60% reported few, if any, recurrent symptoms compared to 70% who received both self-care and conservative treatment. Their self-care instructions recommended the patient use moist heat, massage, exercise, anti-inflammatory medications and soft diet, while avoiding parafunctional habits, stress, overextension of the jaw, unnecessary chewing and poor posture.

McNeill (1993) reports that the success of a self-care program is dependent upon the patient's motivation, cooperation and compliance. He believes a significant factor in patient compliance is the rapport that the patient and the practitioner develop. The practitioner must spend time educating the patient on their disorder and being an attentive listener to the patient's concerns.

CLINICAL TRIAL DESIGN

There are few splint studies which have used randomized assignment of subjects and calibrated evaluators blind to the treatment of the subjects. Most of the literature reporting splint effectiveness consists of anecdotal reports. In a thorough review of the literature, this author has not located any study that evaluated the effectiveness of soft splints on a group of subjects with a primary diagnosis of masticatory muscle disorder. No randomized clinical trials were found assessing the efficacy of palliative treatment for any temporomandibular disorder.

Both subjective and objective outcome assessment are necessary to accurately assess changes in the TMD symptoms with treatment (Okeson et al. 1983). The subjective measurement tool must be multidimensional, consistent and reliable. It should include parameters of sensory, affective intensity, tolerability, frequency and duration of symptoms to adequately evaluate the many dimensions, complexity and variability that occur with typical orofacial pain problems (McGlynn and Cassisi, 1985; Fricton, 1991b). The objective outcome measure should both assess the degree of muscle pain threshold and clinical dysfunction (Okeson et al. 1983; Dahlstrom and Carlsson, 1984; Fricton, 1991b).

The IMPATH: TMJ™ (Medical Metrics, Inc, Minneapolis, MN) is a psychometric instrument designed to determine the severity of symptoms and the impact the problem has on the patient's life (Fricton et al. 1987). It utilizes five simple questions, called the Symptom Severity Index (SSI), to obtain the necessary subjective measurements (Fricton and Schiffman, 1987; Fricton, 1991b). Each of these questions are equally weighted and one question evaluates each of the following areas: sensory intensity, affective intensity, tolerability of symptoms, frequency of symptoms and duration of symptoms. The SSI's questions are listed in Appendix 1. This index is reliable over time and received a Pearson's correlation coefficient of 0.89 for composite scores obtained two to three weeks apart (Fricton, 1990). Its construct validity was confirmed for patient pretreatment and posttreatment scores (Fricton et al. 1987; Fricton and Schiffman, 1987; Fricton, 1990).

The objective outcome measures include muscle pain threshold and

clinical dysfunction (Okeson et al. 1983). Muscle pain threshold can be manually palpated but the inter-rater muscle palpation reliability is unacceptably low, due to the variability of surface area, shape and consistency of the palpating finger and the amount of pressure used (Schiffman et al. 1988). The PAMP II pressure algometer provides a consistent shape, surface area and texture for palpation in addition to accurately measuring the relative pressure. Not only has the PAMP II been shown to produce acceptable inter-rater reliability, but construct validity testing has shown it to performed as expected, with the mean pain thresholds of the normal subjects higher than for subjects with myofascial pain syndrome (Schiffman et al. 1988).

A study with the PAMP II pressure algometer on extra-oral masticatory muscles found that the masseter muscle's superior and inferior areas [referred to in Schiffman et al. (1988) and Chung et al. (1992) as the anterior and inferior masseter muscles respectively] and the anterior temporalis muscle had the best inter-rater reliability between two experienced raters, with Pearson's correlation coefficients of 0.88, 0.89, and 0.93 respectively. These muscle sites also performed very well in the construct validity testing between the normal and myofascial pain syndrome subjects. Chung et al. (1992) corroborated the high inter-rater and intra-rater correlations for the masseter muscle's superior and inferior areas as well as for the anterior temporalis muscle. Schiffman et al. (1988) also highlighted the importance of using experienced raters with a standardized protocol.

The change in the patient's maximum incisor to incisor pain free

opening is an objective outcome measurement for clinical dysfunction that has proven validity for evaluating improvement of TMD patients (Okeson et al. 1982; Okeson et al. 1983).

An expedient and reliable method for evaluating changes in a patient's occlusion was reported by Solberg (1986), Anderson et al. (1993) and Okeson (1993). Differences that have occurred in the patient's ability to hold shimstock (GHM Hanel-Medizinal, Nurtingen, Germany) between their opposing teeth is used to assess occlusal contacts.

This study attempted to identify patients with a primary diagnosis of masticatory muscle disorder, optimize the characteristics of the soft splint, and test the efficacy of the soft splint and palliative treatment in the treatment of masticatory muscle pain. This randomized clinical trial used blinded, calibrated examiners to assess the outcome and to evaluate whether occlusal changes occur with the use of soft splints.

MATERIALS AND METHODS

Thirty consecutive consenting patients from the TMJ and Craniofacial Pain Clinic at the University of Minnesota with the primary diagnosis of masticatory muscle disorder (see inclusion and exclusion criteria, Table 1) were evaluated for baseline measures and randomly assigned to one of the three groups. These groups received the three treatment protocols described below and were scheduled for a follow-up evaluation with the same independent blinded examiner who performed their baseline evaluation.

SUBJECT SELECTION

Potential subjects were recruited at the University of Minnesota's TMJ and Craniofacial Pain Clinic. Patients who fulfilled the inclusion and exclusion criteria were given the opportunity to participate in this study.

Differentiating between a TMJ disorder and a masticatory muscle disorder is straight forward when the patient only has joint or muscle pain. But when the patient has both it can be difficult to determine if the primary diagnosis is a TMJ disorder with protective muscle splinting or the primary diagnosis is a masticatory muscle disorder with concurrent joint pain. It is possible for the patient to have TMJ pain and mechanical symptoms with a primary diagnosis of a masticatory muscle

disorder.

Table 1. CRITERIA FOR ENROLLMENT INTO STUDY:

<u>Inclusion</u>

1) The patient's pain increased with jaw function or parafunctional activity.

2) Tenderness to palpation of the masticatory muscle aggravated the patient's pain.

3) If the patient had TMJ mechanical symptoms, the patient related that these symptoms did not increase their pain complaint.

4) Loading the TMJ in centric relation did not increase the patient's pain.

5) Patient's pain was characteristic of muscle (dull aching pain) rather than of joint (sharp pain) origin.

6) Between the ages of 18 and 80.

<u>Exclusion</u>

1) Concurrent major psychiatric disease.

2) Unwilling to accept any of the three treatment groups randomly assigned.

This study's inclusion criteria set parameters for the patient's complaint that attempted to restrict subjects to those with a primary

diagnosis of a masticatory muscle disorder. The parameters assured the activity that provoked the patient's pain, quality of the pain, aggravation through muscle palpation, and ruled out significant joint disorders by excluding patients who had an increase in their pain with mechanical joint symptoms or pain upon TMJ loading. Okeson et al. (1983); Bell (1986); Thomas and Okeson (1987); Schiffman et al. (1988); Bush et al. (1989) and Okeson (1993) have reported these parameters to be effective in discerning a masticatory muscle disorder.

If the patient met the inclusion and exclusion criteria, the study was explained to the patient, informed consent (see Appendix 2) reviewed and the consent form signed. The patient was then assigned to one of the three groups based on a predetermined random assignment schedule (see Appendix 3). This schedule was prepared prior to the study through a random numbers table so that the assignment of the first and second patients who enrolled in this study were selected by the random numbers table and the third patient was assigned to the group that was not selected. This assignment pattern continued in groups of three until all 30 sequential enrollment positions were assigned. This ensured patients were evenly distributed in the three groups throughout the duration of the study.

STUDY DESIGN

The two independent raters standardized their measuring techniques

and instructions that would be given to the patients prior to the study. Trial measurements were taken on five non-patient subjects in order to establish inter-rater reliability for measuring maximum pain free opening and muscle pain threshold. The examiners had previously been shown to have strong reliability for determining occlusal contact changes assessed with shimstock (Anderson et al. 1993).

The outcome measures were taken at the beginning and the end of the study for each subject and recorded in four categories: 1) Symptom Severity Index (SSI), 2) occlusal contact changes assessed with shimstock, 3) maximum pain free opening and 4) muscle pain threshold using the PAMP II pressure algometer measurements.

Once the subject was enrolled in the study, she or he was first asked to complete the Symptom Severity Index (SSI), see Appendix 1. The SSI uses a total of five questions evaluating: sensory intensity, affective intensity, tolerability of symptoms, frequency of symptoms and duration of symptoms. Since no other IMPATH: TMJ™ indices were used and each question is evenly weighted, an abbreviated variation of this index was used. The first three questions used a 100 mm visual analog scale, their score was calculated by measuring the number of millimeters from the left of the visual analog scale that the patient checked. Since the last two questions used ordinal measures, blocks were provided for the patient to check, with the first block being given a score of 0 and the last block a score of 100. Each question in the SSI had a range of 0 to 100, were evenly weighted and the score for the SSI was calculated by summing the scores for the 5 questions and dividing by 5.

Measuring muscle pain threshold with the PAMP II pressure algometer entailed having the two independent raters agree on the exact location of the palpation sites and exact procedure. The procedure involved: 1) locating the palpation point with gentle index finger pressure; 2) instructing the patient to verbally inform the rater when the pressure from the algometer first became painful; 3) placing the tip of the pressure algometer at that location and increasing the pressure at a rate of 30% of the maximal force per second, until the subject notified the rater that the pressure was painful; and 4) recording the algometer reading and repeating this procedure five seconds later to determine the mean threshold for each location. The readings were entered on the Initial Examination Form (see Appendix 4) and a muscle pain threshold was calculated by summing the average score for each of the 6 muscle sites measured and dividing by 6.

The patient's maximum incisor to incisor pain free opening was measured by asking the patient to open until they first felt pain and measuring the distance between the incisal edges of the maxillary and mandibular central incisors with a millimeter ruler. Since only the change in this measurement over time was analyzed, it was not necessary to add the incisor overlap.

Shimstock was used to determine which maxillary teeth had contact with the opposing mandibular teeth. This was done with the chair positioned at a 45^0 angle, placing shimstock below the maxillary tooth being tested and instructing the patient to close on their back teeth and hold their teeth together. The shimstock was lightly tugged and if

the teeth held it, the maxillary tooth was recorded as having contact with its occlusal antagonist.

The subjects then received the assigned treatments and were scheduled for their final evaluation. The final evaluation was scheduled for 6 weeks later unless there was a scheduling conflict or extenuating circumstances. When the patient returned to the TMJ and Craniofacial Pain Clinic they completed the Symptom Severity Index (SSI) and the same blinded examiner performed the measurements to complete the Final Examination Form (see Appendix 5).

TREATMENT GROUPS

The thirty patients were randomly assigned to one of three groups. The three groups were provided with soft splints, palliative treatment or no treatment (control). The treatment period began with the initial examination and ended with the patient's return to the clinic for final evaluation.

SOFT SPLINT GROUP

The design selected for the soft splints in this study was based on the results of the previously presented studies. The splint design selected was a mandibular full arch coverage with evenly distributed bilateral posterior contacts with light or no contact on the anterior teeth when in centric position. Excursive occlusal guidance provided

posterior disclusion through anterior guidance and vertical dimension was only increased from intercuspal position by approximately 1 mm for improved patient comfort.

Some complications were anticipated for this group based on previous reports. It was felt these complications could be controlled through the following procedures:

1. Possible occlusal changes from wearing the soft splint were minimized by a fabrication technique that pulled a warmed sheet of soft vinyl over a cast of the patient's mandibular arch using a vacuum. This provided a soft splint that tightly adapted to all sides of the mandibular teeth and minimized tooth movement.

2. Bulkiness was minimized by thinning the buccal and lingual flanges of the soft splint to approximately 1 to 2 mm thick, which provided better facial contour of the cheeks and lips as well as allowing more room for the tongue.

3. The difficulty of properly adjusting the appliance occlusion was addressed by evenly warming the occlusal surface of the splint with an alcohol torch, developing the patient's functional occlusal imprint and adjusting the occlusion to the desired occlusal pattern.

A mandibular alginate impression of the patient's mandibular arch

was used to fabricate a baseless cast of quick-set plaster. A sheet of 0.150 inch (2.9 mm) thick resilient mouthguard material (Dentiform mouthguard material 0.150, IDE Interstate, Amityville, NY) was warmed and vacuum suctioned over the trimmed mandibular cast. The edges of the material were trimmed to prevent its over extension into the vestibules or frenum attachments. Care was taken not to overly shorten the posterior lingual flange area and the flanges were thinned to allow for better facial contour of the cheeks and lips in addition to allow more room for the tongue (see Figure 2).

Figure 2. Fabricated soft splint

The appliance was inserted and any area of pressure adjusted. The appliance was replaced on the cast and the occlusal surface of the splint was evenly warmed with an alcohol torch (Alcohol-torch, Hanau, IDE Interstate, Amityville, NY). The splint was inserted in the patient's mouth and a functional imprint was developed in centric, lateral and protrusive excursions, using bilateral centric relation manipulation (Dawson, 1989).

A carbide bur was used to remove the excess material from the imprint. The shiny areas that remained were the pathways the cusp tips formed through the different movements. Centric contacts as well as protrusive and lateral excursions were identified. A guidance on the splint was developed providing posterior disclusion and all other excursive contacts were relieved. Centric occlusion contacts were completed by lightly relieving centric contacts on the anterior teeth. This process evenly distributed bilateral posterior contacts with light or no contact on the anterior teeth in centric position.

Once the splint was adjusted to the practitioner's satisfaction, the patient was asked if the splint felt as if it was occluding evenly on the posterior teeth. If the patient noticed any unevenness in the splint's occlusion, it was adjusted further using articulating paper until the patient felt the splint occluded evenly.

The soft splint was then polished with pumice, disinfected and given to the patient. Patients were instructed to wear the splint 24 hours a day except when eating. Wear and home care instructions were reviewed and given to the patient (see Appendix 6). The patient was scheduled

for their final evaluation and dismissed.

PALLIATIVE TREATMENT GROUP

After the subjects in the palliative treatment group had their Initial Examination Forms completed, they received verbal and written instructions on self-care that they might find useful in reducing their masticatory muscle disorder. These instructions included the use of moist heat or ice, soft diet, decreasing oral parafunctional habits, decreasing the consumption of caffeine, modifying sleeping posture and the use of over-the-counter medications (see Appendix 7). The patient was scheduled for their final evaluation and dismissed.

NO TREATMENT GROUP

The subjects in the no treatment group received no self-care instructions or a soft splint. This is normal clinical procedure practiced for nonemergency TMD patients. As with the other groups, the patient was scheduled an appointment for their final evaluation.

STATISTICAL ANALYSIS

This study used subjective and objective measures to test the effectiveness of palliative treatment, the effectiveness of the soft splint and if occlusal changes occurred with the use of the soft splint. The four null hypotheses tested in this study were:

1. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment in terms of reduction in symptoms, measured by the Symptom Severity Index (SSI).

2. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment in terms of an increase in maximum pain free opening, measured by a millimeter ruler.

3. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment in terms of an increase in pain threshold of the masseter muscle's superior and inferior areas and the anterior temporalis muscle, measured by the pressure algometer.

4. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment in terms of occlusal contact changes as assessed with shimstock.

Pearson correlation coefficients were calculated between each dependent variable to determine if any of the dependent variables were significantly correlated ($r \geq 0.5$). The interdependent variables were then tested as a set using a Multivariate Analysis of Variance to test the null hypotheses that there were no differences among the soft splint

treatment, palliative treatment and no treatment groups. With differences among the groups, a comparison of the three groups was made with the Wilk's lambda test to determine which groups had a statistically significant differences for the set of interdependent variables.

One-way Analysis of Variance was used to test the null hypotheses that there were no differences among soft splint treatment, palliative treatment and no treatment groups, for changes in the SSI, maximum pain free opening and muscle pain threshold. Analysis of Variance was also used to test the null hypothesis that there were no differences among the groups for the teeth with contact changes. For the dependent variables that were found to have a significant difference, comparisons between specific pairs of groups were made using the Student-Newman-Keuls Test.

RESULTS

Strong inter-rater reliabilities were found between the two independent raters prior to the study on the five non-patient subjects. The maximum pain free opening and muscle pain threshold interclass correlations were 0.91 and 0.97 respectively. There was good agreement between the two raters for contact changes assessed with shimstock. They only found one difference in the five non-patient subjects.

Two patients of the original thirty patients did not return for their final evaluations. One patient moved and the second patient assigned to the palliative treatment group related that she was asymptomatic from implementing the palliative treatment instructions and refused to return for fear that the evaluation procedure might cause her symptoms to return. After thirty patients had entered the study, two additional patients were sequentially added to the study and assigned to the groups in the order that the dropouts were originally assigned. This gave each group ten subjects completing the study.

PRETREATMENT CHARACTERISTICS

The thirty patients who completed this study were well matched for gender. All of the participants were female except for four. One male was randomly assigned to both of the treatment groups and the no treatment group received two males.

The age of the participants ranged from 19 to 51 with the mean ages of the soft splint, palliative treatment and no treatment groups were 34, 36 and 31 years old respectively. The treatment period between evaluations ranged from four to eleven weeks, with the treatment periods for the soft splint, palliative treatment and no treatment groups at 6.3, 6.9 and 6.7 weeks respectively.

The three groups were evaluated to determine if there was a statistical difference among groups for: 1) age, 2) the length of time between evaluations, 3) initial SSI scores, 4) initial maximum pain free openings and 5) initial muscle pain threshold scores. There was no significant difference among the groups for these potential confounding factors and initial measures.

CHANGES IN OUTCOME MEASURES

The outcome measures were taken at the beginning and end of the study for each subject and recorded in four categories: 1) the SSI, 2) maximum pain free opening, 3) muscle pain threshold with the pressure algometer and 4) contact changes assessed with shimstock. The outcome measures for each patient are listed in Appendix 8. The initial and final measures for each group are listed in Tables 2 and 3 respectively. The mean changes in outcome measures for each of these groups are summarized in Table 4. The contact changes assessed with shimstock were calculated by adding together 1) the teeth that held shimstock at the

initial examination but not the second examination and 2) the teeth that did not hold shimstock at the initial examination but did at the second examination. The changes for the other measures were calculated by subtracting the final scores from the initial scores.

The Pearson Correlation Coefficients were calculated among each dependent variable for the three groups. Moderate correlations ($r = 0.58$ to 0.64) were found among the change in the three dependent variables SSI, maximum pain free opening and muscle pain threshold, while weak correlations ($r = 0.17$ to 0.42) were found among the dependent variable teeth with contact changes and the other three dependent variables. Therefore, Multivariate Analysis of Variance (MANOVA) was performed for the the change in set of dependent variables SSI, maximum pain free opening and muscle pain threshold. The MANOVA identified a statistically significant difference at an alpha level of 0.05, so the Wilk's lambda test was used to compare the three groups for this set of dependent variables. The Wilk's lambda test found that only the soft splint group was significantly different from the other two groups for the set of three dependent variables at the $P = 0.0001$.

One-way Analysis of Variance (ANOVA) was used to test the null hypotheses that there were no differences among the soft splint treatment, palliative treatment and no treatment groups, for the changes in SSI, maximum pain free opening and muscle pain threshold. ANOVA found that there was statistical difference with all three dependent variables ($P = 0.008$-0.001) at an alpha level of 0.05. The Student-Newman-Keuls Test was used to compare the three groups for each of the

dependent variables and found that for all three dependent variables, the soft splint group was the only group statistically different.

Analysis of Variance was used to test the fourth null hypothesis that the teeth with contact change were not different among the three groups. The ANOVA found there was no statistically significant difference ($P = 0.48$).

Based on these results, the following null hypotheses were rejected:

1. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment groups in terms of reduction in symptoms, measured by the Symptom Severity Index (SSI).

2. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment groups in terms of an increase in maximum pain free opening, measured by a millimeter ruler.

3. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment groups in terms of an increase in pain threshold of the masseter muscle's superior and inferior areas and the anterior temporalis muscle, measured by the pressure algometer.

The fourth null hypothesis was accepted:

4. There is no difference among the responses by subjects given the soft splint, palliative treatment and no treatment groups in terms of the teeth with contact changes as assessed with shimstock.

Table 2. Initial Mean Measures and Standard Deviations (SD)

	Groups		
	Soft Splint	Palliative	No Treatment
Measures	Mean (SD)	Mean (SD)	Mean (SD)
Symptom Severity Index	61.8 (10.8)	61.2 (16.3)	60.7 (21.0)
Maximum Pain Free Opening	37.5 (6.8)	39.9 (10.9)	40.3 (6.3)
Muscle pain threshold	31.3 (11.8)	35.7 (14.9)	41.0 (21.2)

Table 3. Final Mean Measures and Standard Deviations (SD)

	Groups		
	Soft Splint	Palliative	No Treatment
Measures	Mean (SD)	Mean (SD)	Mean (SD)
Symptom Severity Index	32.7 (19.9)	49.4 (18.3)	63.4 (20.1)
Maximum Pain Free Opening	42.4 (6.2)	41.0 (12.4)	40.0 (7.1)
Muscle pain threshold	45.3 (12.7)	35.2 (15.1)	38.1 (22.8)

Table 4. Mean Changes and Standard Deviations (SD) in Measures

	Groups		
	Soft Splint	Palliative	No Treatment
Measures	Mean (SD)	Mean (SD)	Mean (SD)
Symptom Severity Index	-29.1 (22.5)‡	-11.8 (17.0)	2.7 (9.1)
Maximum Pain Free Opening	4.9 (5.0)‡	1.1 (2.5)	-0.3 (2.6)
Muscle pain threshold	14.0 (4.6)‡	0.5 (6.4)	-2.9 (4.7)
Contact Changes	1.3 (1.1)	2.0 (1.9)	1.9 (0.9)

‡ denotes a level of significance $P \leq 0.01$

DISCUSSION

The pretreatment findings are discussed first, followed by changes that were observed in the outcome measures and finally significant clinical applications for use of the soft splints.

PRETREATMENT FINDINGS

All four outcome measures in this study were shown to be reliable and the three measures used by the two independent examiners where shown to be reliable with them. The SSI's reliability has previously been established (Fricton, 1990) and the two independent examiners previously demonstrated their reliability for contact changes assessed with shimstock (Anderson, 1993). The two independent examiners demonstrated strong inter-rater reliabilities with five non-patient subjects prior to the study. Their maximum pain free opening and muscle pain threshold interclass correlations were 0.91 and 0.97 respectively.

There was no significant difference found among the three groups for the possible confounding factors and initial measures of: 1) age, 2) the length of time between evaluations, 3) initial SSI scores, 4) initial maximum pain free openings and 5) initial muscle pain threshold scores.

CHANGES OBSERVED IN MEASURES

An improvement in the patient's muscle disorder was assumed with a negative change in SSI score, positive change in maximum pain free opening score and a positive change in muscle pain threshold. In contrast aggravation of the patient's muscle disorder was related to a positive change in SSI score, negative change in maximum pain free opening score and a negative change in muscle pain threshold.

SYMPTOM SEVERITY INDEX (SSI)

The SSI consists of five simple questions evaluating sensory intensity, affective intensity, tolerability of symptoms, frequency of symptoms and duration of symptoms (see Appendix 1).

The change in SSI scores of the soft splint group was found to be significantly different from the other two groups (P = 0.0012). The mean change for the soft splint, palliative treatment and no treatment were -29.1, -11.8 and 2.7 respectively. These scores appear reasonable since Fricton and Schiffman (1987) reported a mean change in SSI scores of -25 with 24 patients treated for unspecified temporomandibular disorders.

Both the palliative treatment and soft splint groups had nine of ten patients with a change in SSI scores suggestive of improvement in their symptoms. In contrast, only four of the ten patients in the no treatment group rendered change in SSI scores suggestive of improvement in their symptoms.

The finding that 90% of the patients in the soft splint group reported an overall improvement in their symptoms seems reasonable. Clark (1984) reviewed the effectiveness of splint therapy and found that between 70 and 90% of the cases were classified as clinical successes. Wilkinson et al. (1992) reported that 100% of their patients who used their intraoral splint 24 hours a day (as this group was told) had improvement in their headaches.

Harkins et al. (1988) reported 74% had a decrease in symptoms of facial myalgia among the 42 patients who had a primary diagnosis of internal derangement and were treated with a prefabricated soft splint worn for 10 to 20 days. Block et al. (1978) reported 74% of his patients with nonspecific TMD symptoms had complete or almost complete remission of their TMD symptoms after wearing a soft splint for six weeks. Quale et al. (1990) reported that 82% of these patients who suffered from migraine or tension vascular headaches were significantly improved or cured by the use of soft splints.

The finding that 90% of the patients in the palliative treatment group reported an overall improvement in their symptoms also seems reasonable. Randolph et al. (1990) reported that after one to seven years, 60% of the patients to whom they only provided self-care reported having few, if any, recurrent symptoms. Hodges (1990) reported that through his self-care program, 75% of these patients were pain free or comfortable with their problem and management. The designs of these studies were unclear and Hodges (1990) did not specify the length his patients used his self-care program or number of these patients to whom

he also provided splints.

The finding that 60% of the patients in the no treatment group reported change in SSI scores suggestive of worsening of their symptoms and a mean change in SSI scores of 2.7 suggested very slight aggravation of their symptoms. These findings appear reasonable, Harkins et al. (1988) reported that the symptoms in their control group did not appreciably change either.

Although both the palliative treatment and soft splint groups had 9 of 10 patients with scores suggestive of improvement, the quantitative changes in the soft splint group were significantly greater than the palliative treatment group. In fact, as previously discussed the palliative treatment showed no statistical advantage over no treatment using the specified outcome measures.

MAXIMUM PAIN FREE OPENING

The subjects were instructed to open until the first sign of pain and the incisor to incisor measurement in millimeters was compared between the two examinations. The soft splint group's mean change in maximum pain free opening was found to be significantly different from the other two groups (P = 0.0081). The mean change for the soft splint, palliative treatment and no treatment were 4.9, 1.1 and -0.3 respectively and the number of patients in each group who had an increase in their maximum pain free opening was 9, 7 and 4 patients. An increase in the maximum pain free opening was suggestive of improvement for patients with either muscle or joint pain. (Okeson,

1982; Okeson et al. 1983).

The finding that the soft splint group had a mean change of 4.9 mm appears reasonable, but lower than previously reported studies. Okeson et al. (1982) reported that after their patients wore a maxillary flat plane splint for 4 weeks the average maximum pain free opening increased by 5.3 mm. Okeson et al. (1983) reported after their patients wore a maxillary flat plane splint for 6 weeks the average maximum pain free opening increased by 12.4 mm. In contrast patients given only relaxation tapes to aid with relaxation, only increased 2.3 mm.

Although the soft splint treatment and palliative groups respectively had 9 and 7 patients with scores suggestive of improvement, the quantitative changes in the soft splint group were significantly greater than the palliative treatment group. The mean changes for the soft splint group was found to be significantly different from the other two groups and the palliative treatment was not statistically different from the no treatment group.

MUSCLE PAIN THRESHOLD

The soft splint group's mean change in muscle pain threshold was found to be significantly different from the other two groups (P = 0.0001). The mean change for the soft splint, palliative treatment and no treatment were 14.0, 0.5 and -2.9 respectively and the number of patients in each group who had an increase in their muscle pain threshold was 10, 4 and 2 patients. An increase in the pressure that could be applied before it became painful was assumed to be suggestive

of improvement for patients.

The finding that the soft splint group had a mean change of 14.0 appears very reasonable. Schiffman et al. (1988) compared masticatory muscles of myofascial pain patients and normal subjects with a PAMP II pressure algometer. If the differences in these measures for the corresponding areas on females (87% of this study's population) were averaged (as done in this study) the difference would be 39.7 compared to this study's soft splint group's 14.0. This study's change appears comparable with Schiffman et al. (1988) since the soft splint group only wore the splint for an average of 6.3 weeks and even when patients with a masticatory muscle disorder are successfully treated, their muscles do not have as high a muscle pain threshold as subjects without a history of a masticatory muscle disorder (Schiffman et al. 1988).

List et al. (1993) treated patients with a flat plane splint as a control group to compare their improvement with patients treated with acupuncture. Muscle pain threshold with a pressure algometer was one of their outcome measure. The splints were used at night for seven to eight weeks and if the patient responded favorably, they were instructed to use the splint according to personal need and return in 6 months. List et al. (1993) reported that their patients had an increase in muscle pain threshold of 17% compared to a 45% increase in muscle pain threshold found with this study's soft splint group. These results may not be comparable because two different types of pressure algometers were used.

Not only did this study's soft splint group have significantly more

patients with scores suggestive of improvement, but the quantitative scores were also significantly greater than the palliative treatment or no treatment groups.

More subjects in the palliative treatment group showed improvement in their SSI scores compared to their objective measures of maximum pain free opening and muscle pain threshold. This greater subjective improvement relative to objective clinical findings may be related to the high efficacy expectation and doctor-patient interaction with the palliative treatment group. These interactions may have created a placebo effect, producing the high subjective improvement without a corresponding objective improvement (Roberts et al. 1993).

OCCLUSAL CONTACT CHANGES

The occlusal contact changes were assessed with shimstock to evaluate previous reports of occlusal changes observed with soft splints. The soft splint group had fewer contact changes than the other group and there was no statistical difference among the three groups ($P = 0.478$). The mean change for the soft splint, palliative treatment and no treatment were 1.3, 2.0 and 1.9 respectively. The differences seen in contact changes among the groups may be due to the: 1) inherent error with this measurement technique (Anderson, 1993) or 2) variability among the patients. Patient variability could be from the natural movement of teeth throughout the day (Berry and Singh, 1983; Molligoda et al. 1988) or the inability for patients with a masticatory muscle disorder to reproduce occlusal contacts (Edmiston and Laskin, 1978; Capp and

Clayton, 1985; and Suvinen and Reade, 1989).

CLINICAL APPLICATION OF SOFT SPLINT

This study solicited subjective feedback from participants and some observations were made that practitioners may find useful in their clinical practice.

SUBJECTIVE IMPRESSIONS FROM PATIENTS IN SOFT SPLINT GROUP

Once the subjects in the soft splint group completed their second evaluation, subjective opinions were solicited. Subjects were asked: 1) What did you dislike about your soft splint? 2) What improvements do you think could be made with it? 3) Do you want to have the acrylic occlusal splint fabricated, or continue using the soft splint? Those that desired to continue using their soft splint were allowed to do so and were followed for continued effectiveness, attrition and any occlusal changes.

Reasons for disliking the soft splint varied greatly but the most common comment was from three of the ten patients in this group who stated they thought the soft splint was too bulky. This was also the most common complaint received by the patients in Harkins et al. (1988). Two of the patient's comments related to its interference with clear speech and two related to the porosity of the vinyl. One patient was a farmer who found that if he wore the splint while working in areas

with a foul odor, the splint would later a foul taste. The other patient was a heavy smoker and coffee drinker who wore his splint 24 hours a day except when eating and found that cigarette smoke and coffee tended to discolor his splint.

The recommended improvements for the soft splint generally related to correcting the undesirable features, i.e., make splint less bulky, loosen splint, etc. Nine of the ten patients in this group desired to continue using the soft splint rather than changing to an acrylic splint.

A comparison of the splints was made by three patients in the splint group who had previously worn acrylic splints and the one patient who chose to switch to an acrylic splint. All four patients were asked the following questions: 1) Which splint did you find more comfortable and why was it more comfortable? 2) Which splint did you find more effective in relieving your symptoms and why do you think it was more effective? 3) Would you be willing to pay twice as much and wait longer to receive the acrylic splint?

All four of the patients found the soft splint more comfortable than the acrylic splint, three of the patients related that when they inserted their acrylic splint, it placed an uncomfortable pressure on their teeth. Two of the patients related that this was only a temporary discomfort and a third patient related the tightness stayed and made her teeth sore. This finding agrees with reports by Zarrinnia and Lang (1984), Verban (1986), Wright (1988), Giedrys-Leeper (1990) and Shulman and Zeno (1990), that patients prefer the comfort of the soft splint

compared to the acrylic splint.

The three patients who had previously worn acrylic splints found the soft splint more effective and would not be willing to pay twice as much and wait longer to receive an acrylic splint.

POSSIBLE REASONS FOR IMPROVEMENT

Many authors suggest that adjusting the occlusion on soft splints was extremely important to its effectiveness (Krogh-Poulsen and Olsson, 1968; Wright, 1988; Bledsoe, 1991; Messing, 1991). In fact, Krogh-Poulsen and Olsson (1968), Wright (1988) and Bledsoe (1991) recognized the tendency for practitioners to not adjust soft splints and specifically emphasized the importance of this step.

In this study, the occlusion of the soft splint was meticulously adjusted. These findings suggest that the soft splint's occlusion may play a role in its treatment efficacy.

SUBJECTIVE OBSERVATIONS OF SOFT SPLINT GROUP

Two subjective observations were made from the patients assigned to the soft splint group. A soft splint may be able to help predict the success a patient will have with an acrylic splint and there is considerable variation in appliance attrition with long-term use.

All of the patients in the soft splint group, except one, chose to continue using the study soft splint rather than having an acrylic occlusal splint fabricated. The one patient who desired the acrylic splint (patient #4, Appendix 8) had the least improvement in her

subjective and objective measures, except for a college student whose follow-up evaluation was just after her final exams. In addition, patient #4 had the largest change in the teeth that held shimstock, compared to the other members of her group. A mandibular flat plane acrylic splint was constructed, but it was never acceptable to her even after multiple attempts to correct her complaints.

Harkins et al. (1988) found a tendency for the patients who had difficulty with the soft splint to have difficulty with the use of an acrylic splint. Two of his three patients who had an exacerbation of their symptoms with the soft splint or would not wear the soft splint had less than an optimal outcomes with the acrylic occlusal splint. In contrast he found that all of the patients who reported a reduction in symptoms with the soft splint had good to excellent results with the acrylic splint over a three to six month treatment period. Our findings seem in agreement with his observations within the limits of this sample size.

Patients #1 and 2 of the soft splint group returned several times for follow-up appointments enabling an extended assessment of the condition of their splints and occlusal stability. At 31 weeks (7 months), patient #1's soft splint had almost no visible wear and the only sign of patient use was the calculus that had formed on the lingual flange covering her anterior teeth. In contrast, at 22 weeks (5 months), patient #2 had worn several holes in his splint. This patient was informed that an acrylic splint was believed to be more resistant to attrition and in case of severe attrition, additional acrylic could

be added to its occlusal surface. In spite of attempts to persuade the patient, he strongly maintained that if the splint needed to be replaced, he desired replacing it with another soft splint. During this period of observation, greater fluctuations were noted in the occlusal stability of patient #2 compared to patient #1.

Based on this study's limited observations, it appears that complications with long-term use of soft splints may vary for each individual. Patients wearing the soft splint long-term will need to be monitored for attrition of the soft splint and occlusal changes.

CONCLUSIONS

Within the limits of this randomized clinical trial, the following conclusions were suggested:

1. Soft splint treatment was significantly more effective than palliative treatment or no treatment.

2. There was a trend for palliative treatment to be more effective than no treatment but this difference was not statistically significant.

3. Treatment with a soft splint does not appear to cause occlusal changes.

4. Adjustment of the soft splint's occlusion may play a role in its treatment efficacy.

5. Soft splints are comfortable.

The findings of this study suggest that the soft splint is a good interim appliance for reducing the signs and symptoms of patients with a masticatory muscle disorder.

Two additional randomized clinical trials could help answer questions raised by this study. The first clinical trial should be a short-term study comparing an occlusally adjusted soft splint with a

non-occlusally adjusted soft splint for patients with masticatory muscle disorders.

The second should be a long-term study comparing a soft splint with a flat plane acrylic splint for patients with masticatory muscle disorders. This study could suggest: 1) the feasibility of long-term use for a soft splint in terms of patient acceptance, efficacy and attrition, 2) if the soft splint or flat plane acrylic splint is more effective in treating masticatory muscle disorders and 3) additional complications associated with soft splints that practitioners may not be aware of and may not be an issue with the flat plane acrylic splint.

REFERENCES

Ahlin, J.H. (1991) Clinical application of remoldable appliances for craniomandibular disorder. Cranio Clin Int 1:65-79.

Ahlin, J.H. and Atkins, G. (1988) Soft splints and electronic stethoscopic auscultation for the evaluation of TM joint sounds: a preliminary study. Funct Orthod 5:24-6, 39.

Ahlin, J.H. and Atkins, G. (1984) A screening procedure for differentiating temporomandibular joint related headache. Headache 24:216-21.

Anderson, G.C., Schulte, J.K. and Aeppli D.M. (1993) Reliability of the evaluation of occlusal contacts in the intercuspal position. J Prosthet Dent 70:320-3.

Bakke, M. and Michler, L. (1991) Temporalis and masseter muscle activity in patients with anterior open bite and craniomandibular disorders. Scand J Dent Res 99:219-28.

Bates, R.E., Lewis, J.E. and Atkinson, W.B. (1984) Single-appointment occlusal splints. Gen Dent 32:44-46.

Bell, W.E. (1986) *Temporomandibular Disorders: Classification, Diagnosis, Management.* Second Edition. Chicago, Year Book Medical Publishers, pp 218-21.

Bell, W.E. (1989) *Orofacial Pains Classification, Diagnosis, Management.* Fourth Edition. Chicago, Year Book Medical Publishers, pp 158-9.

Belser, U.C. and Hannam, A.G. (1985) The influence of altered working-side occlusal guidance on masticatory muscles and related jaw movement. J Prosthet Dent 53:406-13.

Berry, D.C. and Singh, B.P. (1983) Daily variation in occlusal contacts. J Prosthet Dent 50:386-91.

Bledsoe, S. (1991) Selection, application, and management of Phase 1 orthodontics. Cranio Clin Int 1:13-38.

Block, S.L., Apfel, M. and Laskin, D.M. (1978) The use of a resilient rubber bite appliance in the treatment of MPD syndrome. J Dent Res 57:A71.

Boero, R.P. (1989) The physiology of splint therapy: a literature review. Angle Orthod 59:165-80.

Brayer, L. and Erlich, J. (1976) The nightguard: its uses and dangers of abuse. J Oral Rehab 3:181-4.

Bush, F.M., Whitehill, J.M. and Martelli, M.F. (1989) Pain assessment in temporomandibular disorders. Cranio 7:137-43.

Campbell, J. (1957) Extension of the temporomandibular joint space by methods derived from general orthopedic procedures. J Prosthet Dent 7:386-99.

Capp, N.J. and Clayton, J.A. (1985) A technique for evaluation of centric relation tooth contacts. Part II: Following use of an occlusal splint for treatment of temporomandibular joint dysfunction. J Prosthet Dent 54(5):697-705.

Chung, S., Um, B. and Kim, H. (1992) Evaluation of pressure pain threshold in head and neck muscles by electronic algometer: intrarater and interrater reliability. Cranio 10:28-34.

Clark, G.T. (1984) A critical evaluation of orthopedic interocclusal appliance therapy: design, theory and overall effectiveness for symptoms relief. J Am Dent Assoc 108:359-4.

Clark, G.T., Adachi, N.Y. and Dornan, M.R. (1990a) Physical medicine procedures affect temporomandibular disorders: a review. J Am Dent Assoc 121:151-62.

Clark, G.T., Seligman, D.A., Solberg, W.K. and Pullinger, A.G. (1990b) Guidelines for the treatment of temporomandibular disorders. J Craniomandib Disord 4:80-8.

Colt, J.S. (1991) Occlusal splint therapy in the treatment of temporomandibular disorders: A historical perspective. Cranio Clin Int 1:1-12.

Dahlstrom, L. and Carlsson, S.G. (1984) Treatment of mandibular dysfunction: the clinical usefulness of biofeedback in relation to splint therapy. J Oral Rehabil 11:277-84.

Dahlstrom, L., Haraldson, T. and Janson, S.T. (1985) Comparative electromyographic study of bite plates and stabilization splints. Scand J Dent Res 93:262-8.

Dawson, P.E. (1989) *Evaluation, Diagnosis and Treatment of Occlusal Problems.* Second Edition. St. Louis, CV Mosby Co. pp 41-43, 461-2.

Dawson, P.E. (1973) *Evaluation, Diagnosis and Treatment of Occlusal Problems.* St. Louis, CV Mosby Co. pp 80-100.

Edmiston, G.F. and Laskin, D.M. (1978) Changes in consistency of occlusal contact in myofascial pain-dysfunction (MPD) syndrome. J Dent Res 57(1):27-30.

Fricton, J.R. (1990) Musculoskeletal measures of orofacial pain. Anesth Prog 37:136-43.

Fricton, J.R. (1991a) Recent advances in temporomandibular disorders and orofacial pain. J Am Dent Assoc 122:25-32.

Fricton, J.R. (1991b) Clinical trials for chronic orofacial pain. In Max, M., Portenoy, R. and Laska, E. (eds) *Advances in Pain Research and Therapy*. Vol 18, New York, Raven Press, pp 375-89.

Fricton, J.R. and Schiffman, E.L. (1987) The craniomandibular index: Validity. J Prosthet Dent 58:221-8.

Fricton, J.R., Nelson, A. and Monsein, M. (1987) IMPATH: microcomputer assessment of behavioral and psychosocial factors in craniomandibular disorders. Cranio 5:372-81.

Fricton, J.R., Kroening, R.J. and Hathaway, K.M. (eds), (1988) *TMJ and Craniofacial Pain: Diagnosis and Management*, St Louis: Ishiyaku EuroAmerica, pp 44.

Giedrys-Leeper, E. (1990) Night guards and occlusal splints. Dent Update 17:325-9.

Glass, E.G., McGlynn, F.D. and Glaros, A.G. (1991) A survey of treatments for myofascial pain dysfunction. Cranio 9:165-8.

Goodwillie D.H. (1881) Arthritis of the temporomaxillary articulation. Arch Med 5:259-63.

Graham, G.S. and Rugh, J.D. (1988) Maxillary splint occlusal guidance patterns and electromyographic activity of the jaw-closing muscles. J Prosthet Dent 59:73-7.

Guinn, J.L. and Williams, B.T. (1985) Choosing the right appliance. Cranio 3:289-93.

Hagberg, C. and Hagberg, M. (1988) Surface EMG frequency dependence on force in the masseter and the anterior temporal muscles. Scand J Dent Res 96:451-6.

Hampf, G. (1992) A new clinical approach to the treatment of temporomandibular dysfunction and orofacial dysesthesia: Natural history and comparisons with similar chronic pain conditions. J Craniomandib Disord Facial Oral Pain 6:56-63.

Hannam, A.G. (1982) The innervation of the periodontal ligament. In Berkovitz, B. K., Moxham, B. J. and Newman, H. N. (eds) *The Periodontal Ligament in Health and Disease.* New York, Pergamon Press, pp 173-96.

Harkins, S., Marteney, J.L., Cueva, O. and Cueva, L. (1988) Application of soft occlusal splints in patients suffering from clicking temporomandibular joints. Cranio 6:71-6.

Hicks, N.A. (1989) An efficient method for constructing a soft interocclusal splint. J Prosthet Dent 61:48-50.

Hodges, J.M. (1990) Managing temporomandibular joint syndrome. Laryngoscope 100(1):60-6.

Ito, T., Gibbs, C.H., Marguelles-Bonnet, R., Lupkiewicz, S.M., Young, H.M., Lundeen, H.C. and Mahan, P.E. (1986) Loading on the temporomandibular joints with five occlusal conditions. J Prosthet Dent 56:478-84.

Klineberg, I. (1991) *Craniomandibular Disorders and Orofacial Pain, Diagnosis and Management.* Avon, Great Britain, Bath Press, pp 102-3.

Krogh-Poulsen, W.G. and Olsson, A. (1968) Management of the occlusion of the teeth. In Schwartz, L. and Chayes, C.M. (eds) *Facial Pain and Mandibular Dysfunction.* Philadelphia, WB Saunders Co, pp 275.

Lerman, M.D. (1987) The hydrostatic splint: new muscle-directed TMJ-PDS treatment technique. CDS Rev 80:31-4.

List, T. and Helkimo, M. (1992) Adverse events of acupuncture and occlusal therapy in the treatment of craniomandibular disorders. Cranio 10:318-26.

List, T., Helkimo, M. and Karlsson R. (1993) Pressure pain thresholds in patients with craniomandibular disorders before and after treatment with acupuncture and occlusal splint therapy: A controlled clinical study. J Orofacial Pain 7:275-282.

MacDonald, J.W. and Hannam, A.G. (1984) Relationship between occlusal contacts and jaw-closing muscle activity during tooth clenching: Part I. J Prosthet Dent 52:718-28.

Manns, A., Miralles, R., Santander, H. and Valdivia, J. (1983) Influence of the vertical dimension in the treatment of myofascial pain-dysfunction syndrome. J Prosthet Dent 50:700-9.

Manns, A., Chan, C. and Miralles, R. (1987) Influence of group function and canine guidance on electromyographic activity of elevator muscles. J Prosthet Dent 57:494-501.

Manns, A., Garcia, C., Miralles, R., Bull, R. and Rocabado, M. (1991) Blocking of periodontal afferents with anesthesia and its influence on elevator EMG activity. Cranio 9:212-9.

Mason, P., Strassman, A. and Maciewicz, R. (1985) Is the jaw-opening reflex a valid model of pain? Brain Res 357:137-46.

McGivney, G.P. and Castleberry, D.J. (1989) *McCracken's Removable Partial Prosthodontics*. St. Louis, CV Mosby Co, pp 91.

McGlynn, F.D. and Cassisi, J.E. (1985) An intrasubject replication strategy for evaluating occlusal splint therapy. Cranio 3:280-6.

McNeill C. (1993) *Temporomandibular Disorders: Guidelines for Classification, Assessment, and Management*. 2nd Ed. Chicago, Quintessence Publishing Co, pp 82-3.

Messing, S.G. (1991) Splint therapy. In Kaplan, A.S. and Assael, L.A. (eds), *Temporomandibular Disorders, Diagnosis and Treatment*. Philadelphia, WB Saunders Co, pp 433-5.

Miralles, R., Manns, A., Nass, X., Pasini, C. and Rocabado, M. (1987) Influence of protrusive functions on electromyographic activity of elevator muscles. Cranio 5:324-32.

Miralles, R., Manns, A. and Pasini, C. (1988) Influence of different centric functions on electromyographic activity of elevator muscles. Cranio 6:26-33.

Molligoda M. A., Abuzar, M. and Berry, D.C. (1988) Measuring diurnal variation in the dispersion of occlusal contacts. J Prosthet Dent 60:235-8.

Nevarro, E., Barghi, N. and Rey, R. (1985) Clinical evaluation of maxillary hard and resilient occlusal splints. J Dent Res (Special Issue) 64:313, abstract no. 1246.

Okeson, J.P. (1993) *Management of Temporomandibular Disorders and Occlusion*. 3rd Ed. St. Louis, CV Mosby Co, pp 263, 272, 295, 305-8 & 488.

Okeson, J.P. (1987) The effects of hard and soft occlusal splints on nocturnal bruxism. J Am Dent Assoc 114:788-91.

Okeson, J.P., Kemper, J.T. and Moody P.M. (1982) A study of the use of occlusion splints in the treatment of acute and chronic patents with craniomandibular disorders. J Prosthet Dent 48:708-12.

Okeson, J.P., Moody, P.M., Kemper, J.T. and Calhoun, T.C. (1983)

Evaluation of occlusal splint therapy. J Craniomandibular Pract 1:47-52.

Pertes, R.A. and Cohen, H.V. (1992) Guidelines for clinical management of temporomandibular disorders: Part 1. Compendium 13:268-76.

Posselt, U. and Wolf, I.B. (1963) Treatment of bruxism by bite guards and bite plates. J Can Dent Assoc 29:773-8.

Quayle, A.A., Gray, R.J., Metcalfe, R.J., Guthrie, E. and Wastell, D. (1990) Soft occlusal splint therapy in the treatment of migraine and other headaches. J Dent 18:123-9.

Randolph, C.S., Greene, C.S., Moretti, R., Forbes, D. and Perry, H.T. (1990) Conservative management of temporomandibular disorders: a posttreatment comparison between patients from a university clinic and from private practice. Am J Orthod Dentofacial Orthop 98:77-82.

Roberts, A.H., Kewman, D.G., Mercier, L. and Hovell, M. (1993). The power of nonspecific effects in healing: Implications for psychosocial and biological treatments. Clin Psych Rev 13:375-91.

Rugh, J.D., Graham, G.S., Smith, J.C. and Ohrbach, R.K. (1989) Effects of canine versus molar occlusal splint guidance on nocturnal bruxism and craniomandibular symptomatology. J Craniomandib Disord 3:203-10.

Schiffman, E., Fricton, J., Haley, D. and Tylka, D. (1988) A pressure algometer for myofascial pain syndrome: reliability and validity testing. In Dubner, R., Gebhart, G.F. and Bond, M.R. (eds) *Proceedings of the Vth World Congress on Pain.* Philadelphia, Elsevier Science Publishers, pp 408-13.

Shulman, J. and Zeno, A. (1990) A new technique for making occlusal devices. J Prosthet Dent 63:482-5.

Shupe, R.J., Mohamed, S.E., Christensen, L.V., Finger, I.M. and Weinberg, R. (1984) Effects of occlusal guidance on jaw muscle activity. J Prosthet Dent 51:811-8.

Singh, B.P. and Berry, D.C. (1985) Occlusal changes following use of soft occlusal splints. J Prosthet Dent 54:711-5.

Solberg, W.K. (1986) Temporomandibular disorders: data collection and examination. Br Dent J 160:317-22.

Suvinen, T. and Reade, P. (1989) Prognostic features of value in the management of temporomandibular joint pain-dysfunction syndrome by occlusal splint therapy. J Prosthet Dent 61(3):355-61.

Taddey, J.J. (1990) Rationale for sequential use of both maxillary and

mandibular orthopedic appliances in the treatment of TMJ disorders. J Craniomandib Disord 4:273-5.

Tanner, H. (1980) The Tanner mandibular appliance. Continuum 1980:23-34.

Thomas, C.A. and Okeson, J.P. (1987) Evaluation of lateral pterygoid muscle symptoms using a common palpation technique and a method of functional manipulation. J Craniomandibular Pract 5:125-9.

Van Steenberghe, D. and De Vries, J.H. (1978) The influence of local anesthesia and occlusal surface area on the forces developed during repetitive maximal clenching efforts. J Periodontal Res 13:270-74.

Verban, E. (1986) A self-adjusting TMJ appliance. CDS Rev 79:38-43.

Widmer, C.G., Lund, J.P. and Feine, J.S. (1990) Evaluation of diagnostic tests for TMD. J Calif Dent Assoc 18:53-60.

Wilkinson, T., Hansson, T., McNeill, C. and Marcel, T. (1992) A comparison of the success of 24-hour occlusal splint therapy versus nocturnal occlusal splint therapy in reducing craniomandibular disorders. J Craniomandibular Disord 6:64-70.

Williams, W.B. (1991) Pain release splint. Cranio Clin Int 1:55-64.

Williamson, E.H. and Lundquist, D.O. (1983) Anterior guidance: its effect on electromyographic activity of the temporal and masseter muscles. J Prosthet Dent 49:816-23.

Wood, W.W. and Tobias, D.L. (1984) EMG response to alteration of tooth contacts on occlusal splints during maximal clenching. J Prosthet Dent 51:394-6.

Wright, E.F. (1988) An easily fabricated occlusal splint. J Am Dent Assoc 117:757-8.

Zarrinnia, K. and Lang, K.S. (1984) A therapeutic method for selected TMJ dysfunction patients. J Clin Orthod 18:35-7.

APPENDIX 1

SYMPTOM SEVERITY INDEX (SSI)

To determine the extent of your symptoms, would you please place an "X" on the line or in one of the blocks for each of the following questions. Thank you.

1. How intense are your symptoms?

Zero — The most that can be imagined

2. How unpleasant or disturbing is your usual level of symptoms?

Zero — The most that can be imagined

3. How difficult is it to endure the problem over time?

No difficulty — The most that can be imagined

4. How often do the symptoms generally occur?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Never 1/month 1/day 1/hour 1/minute constant

5. When the symptoms occur, how long do the symptoms usually last?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Never 1 minute 1 hour 1 day 1 month or

APPENDIX 2

CONSENT FORM

for

THE SHORT-TERM EVALUATION OF SOFT MOUTHGUARDS

You are invited to be in a research study evaluating the effectiveness of soft mouthguards for patients with jaw muscle pain. You were selected as a possible participant because your primary diagnosis is pain from your jaw muscles. We ask that you read this form and ask any questions you may have before agreeing to be in this study. This study is being conducted by the University of Minnesota's TMJ and Craniofacial Pain Clinic.

BACKGROUND INFORMATION:

The purpose of this study is to determine the effectiveness of soft mouthguards for patients who have jaw muscle pain.

Most insurance companies require "prior authorization" before they will pay for jaw muscle treatment and this study will help us to determine what treatment would be most beneficial for our patients during this interim period.

We are asking patients with this disorder to volunteer to be one of 30 patients who will be randomly assigned into three groups. One group will receive a soft mouthguard, another will receive palliative treatment and the third will not receive palliative treatment (what we presently do). Random assignment is by chance, like flipping a coin, so there is a one in three chance that you will be assigned to any one of these three groups.

PROCEDURES:

If you agree to be in the study, we would ask you to do the following things:

1. Today we will ask you to:
    a. Answer a few questions about your pain.
    b. Have a brief exam of your jaw and its movement.
    c. If you are assigned to the soft mouthguard group, we will take an impression of your lower teeth, make the mouthguard (takes about 45 minutes) and adjust it to fit your bite.
    d. If you are selected for the palliative treatment group, we will

work with you on managing your disorder through procedures that you can do at home to relax your jaw muscles and joints to help reduce your jaw pain.

2. Once you receive the "prior authorization" from your insurance company,
schedule an appointment with Dr. Wright to record your final symptoms and muscle tenderness in conjunction with the other treatment he has outlined for you.

3. If you do not receive the "prior authorization," if you desire, you may still receive the treatment outlined for you and participate in this study, but you would be responsible for payment of your treatment.

RISKS AND BENEFITS OF BEING IN THE STUDY:

No risk is expected as a result of this study's activities, other than the risk assumed by all patients treated at this clinic who receive this care. The benefits from either group can range from no improvement to complete relief of your symptoms.

You will receive no money for participating in this study.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY:

The alternative to participating in this study would be to wait until your insurance company approves your "prior authorization" and receive your care at that time.

COMPENSATION:

In the event that this activity results in a physical injury, medical treatment will be available, including first aid, emergency treatment and follow-up care. Payment for this treatment must be provided by you or your third party payor, if any.

CONFIDENTIALITY:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject.

VOLUNTARY NATURE OF THE STUDY:

Your decision whether or not to participate will not affect your

current or future relation with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relations.

NEW INFORMATION:

If during the course of this research study, there are significant new findings discovered which might influence your willingness to continue, the researchers will inform you of these developments.

CONTACTS AND QUESTIONS:

The researchers conducting this study are Drs. Edward Wright, John Schulte and Gary Anderson. You may ask any questions you have now. If you have questions later, you may contact them at the University of Minnesota; Phone: Dr. Wright (612) 626-0140; Dr. Schulte (612) 625-7954; Dr. Anderson (612) 624-3908.

You will be given a copy of this form for your records.

STATEMENT OF CONSENT:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature ______________________________________ Date ____________

APPENDIX 3

RANDOMIZED SEQUENCE OF GROUP ASSIGNMENT

Group A = Soft Splint

Group B = Palliative Treatment

Group C = No Treatment

Patient #:	1,	2,	3	4,	5,	6	7,	8,	9	10,	11,	12
Group Assn:	B	C	A	A	B	C	C	B	A	A	C	B
Patient #:	13,	14,	15	16,	17,	18	19,	20,	21	22,	23,	24
Group Assn:	A	C	B	C	A	B	B	A	C	B	C	A
Patient #:	25,	26,	27	28,	29,	30						
Group Assn:	B	C	A	C	B	A						

Note:

Made from randomization table, where:
1,4,7 = A
2,5,8 = B
3,6,9 = C

APPENDIX 4

INITIAL EXAMINATION FORM

Patient # ___

Maxillary teeth that hold shimstock:
- Chair at 45^0 angle, "close on your back teeth, close and hold"

Rt	3M	2M	1M	2P	1P	C	L	I	I	L	C	1P	2P	1M	2M	3M	Lt

Maximum pain free opening ___ mm.
- Interincisal opening, "open until you feel pain"

Pressure pain thresholds:
- "tell me when you first feel pain"

	Rt	Lt
Anterior temporalis muscle	___	___
Masseter, superior area	___	___
Masseter, inferior area	___	___

APPENDIX 5

FINAL EXAMINATION FORM

Patient # ___

Maxillary teeth that hold shimstock:
- Chair at 45^0 angle, "close on your back teeth, close and hold"

<u>Rt</u> 3M 2M 1M 2P 1P C L I I L C 1P 2P 1M 2M 3M <u>Lt</u>

Maximum pain free opening ___ mm.
- Interincisal opening, "open until you feel pain"

Pressure pain thresholds:
- "tell me when you first feel pain"

	Rt	Lt
Anterior temporalis muscle	____	____
Masseter, superior area	____	____
Masseter, inferior area	____	____

APPENDIX 6

INSTRUCTIONS FOR SOFT SPLINT GROUP

Your soft splint has been specifically designed to help your jaw muscles heal. Please follow these guidelines:

1. Over the first couple of days, gradually increase your use of the splint so that you are wearing it all of the time, except when you eat. If it gives you any pain, call Dr. Wright at 626-0140 so he can make arrangements to adjust it.

2. Do not bite down on the splint. Keep your teeth apart and your tongue up. The splint is most effective if you only close lightly on it when you swallow.

3. At least once a day clean the inside and outside of the splint with your toothbrush and toothpaste. Some people like to soak it in mouthwash when they are not wearing it.

4. If you go to a restaurant to eat, don't roll it up in a napkin and lay it on the table, you will probably leave it behind. When eating at home, keep it out of your pet's reach, dogs love to chew on them!

APPENDIX 7

INSTRUCTIONS FOR PALLIATIVE TREATMENT GROUP

We use our mouths for so many activities (talking, eating, yawning, laughing) that when we are not engaged in these, we need to allow our jaw muscles and joints to relax. Many people have developed habits that do not permit their muscles or joints to relax a sufficient amount of time. The following will help instruct you on how to relax your jaw muscles and joints to reduce the jaw pain you are having:

1. Apply moist heat or ice to the painful areas, most people prefer moist heat but if it increases your pain, use ice.

   a. Use moist heat for 20 minutes two or four times each day. Moist heat can be obtained by wetting a towel with very warm water. It can be kept warm by wrapping it around a hot water bottle or placing a piece of plastic wrap and heating pad over it. It also can be rewarmed in a microwave oven or under the very warm water.

   b. Apply ice wrapped in a thin washcloth to the painful area until you first feel some numbness then remove it (usually takes about 10 minutes).

2. Eat soft foods like casseroles, canned fruit, soups, eggs and yogurt. Don't chew gum or eat hard (raw carrots) or chewy foods (caramels, steak, bagels). Cut other food into small pieces and try to chew on both sides or alternating sides of your mouth.

3. Rest your jaw muscles by keeping your teeth apart. Your teeth should never touch except lightly when you swallow. Closely monitor yourself for the habit of clenching that you may have developed. People will often do this when they are driving the car or concentrating. Try keeping your jaw relaxed by placing your tongue lightly behind your upper front teeth, having your jaw in a comfortable position with your teeth apart and relaxing your jaw muscles.

4. Avoid caffeine, because it stimulates your muscles to contract and hold more tension in them. Caffeine or caffeine-like drugs are in coffee, tea, most sodas, and chocolate. Decaffeinated coffee has half the amount of caffeine as regular coffee and Sanka has none.

5. Avoid habits that strain your jaw muscles and joints, such as clenching, grinding or resting you teeth together; biting you cheeks, lips, or objects you put in your mouth; pushing your tongue against your teeth or holding your jaw in an uncomfortable or tense position.

6. Avoid sleeping habits that strain your jaw muscles or joints, by not

sleeping on your stomach and if you sleep on you side, keeping you neck and jaw aligned.

7. Restrain from opening your mouth wide, such as yawning, yelling or prolonged dental procedures.

8. Use anti-inflammatory and pain reducing medications such as ibuprofen, Tylenol and aspirin to reduce joint and muscle pain. Avoid those with caffeine, e.g. Anacin and Excedrin.

APPENDIX 8

OUTCOME SCORES AND PATIENT FEATURES

Group: Soft Splint **Patient #:** 1

Age: 49 **Weeks of Treatment:** 6

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	67.0	27.4	-39.6
Maximum Pain Free Opening	48	51	3
Muscle pain threshold	30.4	41.3	10.9
Teeth Holding Shimstock			2

Group: Soft Splint **Patient #:** 2

Age: 35 **Weeks of Treatment:** 4

	Scores		
Measures	Initial	**Final**	Difference
Symptom Severity Index	62.0	29.6	-32.4
Maximum Pain Free Opening	26	38	12
Muscle pain threshold	41.3	53.3	12.0
Teeth Holding Shimstock			2

Group: Soft Splint **Patient #:** 3

Age: 23 **Weeks of Treatment:** 5

	Scores		
Measures	Initial	**Final**	Difference
Symptom Severity Index	60.4	39.8	-20.6
Maximum Pain Free Opening	35	40	5
Muscle pain threshold	20.0	34.2	14.2
Teeth Holding Shimstock			2

Group: Soft Splint **Patient #:** 4

Age: 47 **Weeks of Treatment:** 6

	Scores		
Measures	**Initial**	**Final**	**Difference**
Symptom Severity Index	44.0	31.0	-13.0
Maximum Pain Free Opening	48	49	1
Muscle pain threshold	27.5	37.5	10.0
Teeth Holding Shimstock			3

Group: Soft Splint **Patient #:** 5

Age: 39 **Weeks of Treatment:** 5

	Scores		
Measures	**Initial**	**Final**	**Difference**
Symptom Severity Index	50.0	15.2	-34.8
Maximum Pain Free Opening	40	45	5
Muscle pain threshold	53.3	70.0	16.7
Teeth Holding Shimstock			0

Group: Soft Splint **Patient #:** 6

Age: 21 **Weeks of Treatment:** 7

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	77.0	17.4	-59.6
Maximum Pain Free Opening	32	41	9
Muscle pain threshold	28.3	47.1	18.8
Teeth Holding Shimstock			1

Group: Soft Splint **Patient #:** 7

Age: 29 **Weeks of Treatment:** 11

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	78.0	25.2	-52.8
Maximum Pain Free Opening	37	41	4
Muscle pain threshold	28.3	47.1	18.8
Teeth Holding Shimstock			0

Group: Soft Splint **Patient #:** 8

Age: 34 **Weeks of Treatment:** 7

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	60.6	25.4	-35.2
Maximum Pain Free Opening	35	46	11
Muscle pain threshold	29.6	50.4	20.8
Teeth Holding Shimstock			0

Group: Soft Splint **Patient #:** 9

Age: 48 **Weeks of Treatment:** 6

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	65.2	41.2	-24.0
Maximum Pain Free Opening	40	44	4
Muscle pain threshold	11.7	22.5	10.8
Teeth Holding Shimstock			2

Group: Soft Splint   Patient #: 10

Age: 34   Weeks of Treatment: 6

	Scores		
Measures	Initial	Final	Difference
Symptom Severity Index	53.6	74.6	21.0
Maximum Pain Free Opening	34	29	-5
Muscle pain threshold	42.5	49.2	6.7
Teeth Holding Shimstock			1

Group: Palliative Treatment   Patient #: 1

Age: 37   Weeks of Treatment: 6

	Scores		
Measures	Initial	Final	Difference
Symptom Severity Index	54.8	36.0	-18.8
Maximum Pain Free Opening	36	35	-1
Muscle pain threshold	32.5	29.6	-2.9
Teeth Holding Shimstock			3

Group: Palliative Treatment **Patient #:** 2

Age: 44 **Weeks of Treatment:** 10

Measures	**Scores** Initial	Final	Difference
Symptom Severity Index	81.8	66.0	-15.8
Maximum Pain Free Opening	51	57	6
Muscle pain threshold	34.5	32.9	-1.6
Teeth Holding Shimstock			6

Group: Palliative Treatment **Patient #:** 3

Age: 45 **Weeks of Treatment:** 8

Measures	**Scores** Initial	Final	Difference
Symptom Severity Index	53.4	75.0	21.6
Maximum Pain Free Opening	52	55	3
Muscle pain threshold	57.9	48.7	-9.2
Teeth Holding Shimstock			1

Group: Palliative Treatment **Patient #:** 4

Age: 21 **Weeks of Treatment:** 7

Measures	Scores Initial	Final	Difference
Symptom Severity Index	51.0	26.8	-24.2
Maximum Pain Free Opening	38	39	1
Muscle pain threshold	25.4	21.7	-3.7
Teeth Holding Shimstock			0

Group: Palliative Treatment **Patient #:** 5

Age: 41 **Weeks of Treatment:** 10

Measures	Scores Initial	Final	Difference
Symptom Severity Index	44.8	37.6	-7.2
Maximum Pain Free Opening	45	46	1
Muscle pain threshold	33.3	36.7	3.4
Teeth Holding Shimstock			4

Group: Palliative Treatment **Patient #:** 6

Age: 37 **Weeks of Treatment:** 7

Measures	Scores: Initial	Final	Difference
Symptom Severity Index	74.8	31.8	-43.0
Maximum Pain Free Opening	43	45	2
Muscle pain threshold	24.2	22.9	-1.3
Teeth Holding Shimstock			0

Group: Palliative Treatment **Patient #:** 7

Age: 43 **Weeks of Treatment:** 5

Measures	Scores: Initial	Final	Difference
Symptom Severity Index	84.0	63.8	-20.2
Maximum Pain Free Opening	38	39	1
Muscle pain threshold	67.5	70.4	2.9
Teeth Holding Shimstock			2

Group: Palliative Treatment **Patient #:** 8

Age: 24 **Weeks of Treatment:** 6

Measures	Scores Initial	Final	Difference
Symptom Severity Index	70.4	66.2	-4.2
Maximum Pain Free Opening	25	27	2
Muscle pain threshold	31.3	32.1	0.8
Teeth Holding Shimstock			2

Group: Palliative Treatment **Patient #:** 9

Age: 35 **Weeks of Treatment:** 6

Measures	Scores Initial	Final	Difference
Symptom Severity Index	34.6	30.6	-3.8
Maximum Pain Free Opening	51	50	-1
Muscle pain threshold	26.7	19.2	-7.5
Teeth Holding Shimstock			2

Group: Palliative Treatment **Patient #:** 10

Age: 34 **Weeks of Treatment:** 4

Measures	Scores Initial	Final	Difference
Symptom Severity Index	62.2	59.8	-2.4
Maximum Pain Free Opening	20	17	-3
Muscle pain threshold	23.8	37.5	13.7
Teeth Holding Shimstock			0

Group: No Treatment **Patient #:** 1

Age: 27 **Weeks of Treatment:** 10

Measures	Scores Initial	Final	Difference
Symptom Severity Index	40.6	55.2	14.6
Maximum Pain Free Opening	39	42	3
Muscle pain threshold	33.8	27.9	-5.9
Teeth Holding Shimstock			0

Group: No Treatment

Patient #: 2

Age: 51

Weeks of Treatment: 6

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	77.4	66.8	-10.6
Maximum Pain Free Opening	36	32	-4
Muscle pain threshold	48.3	43.3	-5.0
Teeth Holding Shimstock			2

Group: No Treatment

Patient #: 3

Age: 22

Weeks of Treatment: 7

Measures	Initial	Final	Difference
	Scores		
Symptom Severity Index	74.2	79.4	5.2
Maximum Pain Free Opening	32	30	-2
Muscle pain threshold	20.4	10.0	-10.4
Teeth Holding Shimstock			2

Group: No Treatment　　**Patient #:** 4

Age: 40　　**Weeks of Treatment:** 8

Measures	Scores Initial	Final	Difference
Symptom Severity Index	61.2	75.4	14.2
Maximum Pain Free Opening	43	42	-1
Muscle pain threshold	28.8	27.1	-1.7
Teeth Holding Shimstock			1

Group: No Treatment　　**Patient #:** 5

Age: 31　　**Weeks of Treatment:** 6

Measures	Scores Initial	Final	Difference
Symptom Severity Index	78.0	72.4	-5.6
Maximum Pain Free Opening	43	39	-4
Muscle pain threshold	28.3	21.7	-6.6
Teeth Holding Shimstock			2

Group: No Treatment **Patient #:** 6

Age: 31 **Weeks of Treatment:** 8

Measures	Scores Initial	Final	Difference
Symptom Severity Index	47.2	49.2	2.0
Maximum Pain Free Opening	35	38	3
Muscle pain threshold	35.8	40.8	5.0
Teeth Holding Shimstock			3

Group: No Treatment **Patient #:** 7

Age: 26 **Weeks of Treatment:** 6

Measures	Scores Initial	Final	Difference
Symptom Severity Index	44.0	57.0	13.0
Maximum Pain Free Opening	34	33	-1
Muscle pain threshold	25.4	22.1	-3.3
Teeth Holding Shimstock			2

Group: No Treatment | **Patient #:** 8
Age: 33 | **Weeks of Treatment:** 4

	Scores		
Measures	**Initial**	**Final**	**Difference**
Symptom Severity Index	22.4	16.6	-5.8
Maximum Pain Free Opening	47	49	2
Muscle pain threshold	56.3	52.5	-3.8
Teeth Holding Shimstock			2

Group: No Treatment | **Patient #:** 9
Age: 25 | **Weeks of Treatment:** 6

	Scores		
Measures	**Initial**	**Final**	**Difference**
Symptom Severity Index	87.4	84.4	-3.0
Maximum Pain Free Opening	42	43	1
Muscle pain threshold	40.4	44.2	3.8
Teeth Holding Shimstock			3

Group: No Treatment **Patient #:** 10

Age: 20 **Weeks of Treatment:** 6

Measures	Scores		
	Initial	Final	Difference
Symptom Severity Index	74.2	77.4	3.2
Maximum Pain Free Opening	52	52	0
Muscle pain threshold	92.9	91.7	-1.2
Teeth Holding Shimstock			2